# HUMAN BIOELECTRIC SIGNAL SIMULATOR

## Cross-Reference to Related Applications

Not Applicable.

## Technical Field

The present invention is related generally to medical training devices, and in particular, to a medical training device configured to provide simulated bioelectrical signals such as evoked auditory signals and EEG signals associated with medical screening practices such as infant hearing testing, facilitating training and detection of abnormal medical conditions.

## Background Art

The measuring or monitoring of evoked or continuous bioelectric signals in a patient, such as an infant or other human patient who may be incapable of audiometric behavioral responses, is becoming an increasingly common method for initial patient screening or monitoring, and is used in auditory testing programs to identify hearing abnormalities, or in anesthesia and sedation monitoring to determine a patient's state, such as an awareness level.

In auditory screening, the functionality of the outer hair cells of the inner ear can be assessed with measurements of sounds in the external ear canal generated by the inner ear, called otoacoustic emissions (OAE), in response to clicks, called transient evoked OAE (TEOAE), or to two tones, called distortion product OAE (DPOAE).

As shown in Figure 1, a TEOAE is generated in response to a transient test signal, usually a sequence of square waves (click). The level of these clicks is typically between 35 dB SPL and 90 dB SPL. In response to these test signals, a normal human ear generates a wide band signal up to 20 ms in duration after each click. As shown in Figure 1, the spectrum $S_T$ of this response can be compared against the spectrum of ambient noise $S_A$ to identify normal or abnormal hearing.

Similarly, as shown in Figure 2, a DPOAE is generated in response to the presentation of two simultaneous tonal signals, $s_1$ and $s_2$ with associated frequencies $f_1$, and $f_2$, with $f_2 > f_2$. Typically, the ratio of the frequency of $f_2$ to $f_1$

is selected to be about 1.2, with amplitudes $|s_1|$= 65 dB SPL and $|s_2|$= 55 db SPL in the ear canal. In response to these signals, a normal human ear generates, among others, a third tonal signal, the DPOAE at frequency 2f1-f2, which can be measured to identify normal or abnormal hearing.

Surface electrodes are utilized to detect bioelectric signals in a patient which are generated in response to an auditory stimulus. These bioelectric signals can be used both in auditory screening and in brain activity monitoring during anesthesia or sedation. An auditory evoked potential (AEP) is produced upon presentation of an auditory stimulus or series of stimuli, such as clicks or tone bursts. The AEP can be characterized by three components which refer to the latency of the response with respect to the stimulus; these are referred to as early, middle, and late components.

The early or short latency component of the AEP, the auditory brainstem response (ABR), occurs within the first 15ms after the presentation of the auditory stimulus and is widely used for clinical evaluation of hearing in infants and other individuals who are unable to effectively communicate whether a sound was detected. In individuals with normal hearing, the ABR generates a characteristic neural waveform shown in Figure 3. Auditory testing using the ABR typically involves a visual or statistical comparison of a tested individual's waveform to a normal template waveform. Like other evoked potentials, the ABR is recorded from surface electrodes on the scalp. However, the electrodes also record the background noise comprised of unwanted bio-potentials resulting from other neural activity, muscle activity, and unwanted non-physiological sources in the environment.

The middle component of the AEP, the auditory mid-latency response (AMLR), also referred to as the middle latency auditory evoked potential (MLAEP) occurs 15ms – 100ms after the presentation of the auditory stimulus, and is believed to reflect primary, non-cognitive, cortical processing of auditory stimuli. Lately, the AMLR, or MLAEP, has been of particular interest as a measure of depth of anesthesia.

It is known that the AMLR consists of positive and negative waves that are sensitive to sedatives and anesthetics. In general, increasing the level of sedation or anesthetic increases the latency of these waves, and simultaneously decreases the amplitudes. For monitoring purposes, changes in the AMLR waves are quantified as latency to peak, amplitude, and rate of change, and are sometimes combined in a single index.

Another component of the AEP, the auditory late response (ALR) occurs about 100ms after the auditory stimulus, and is believed to be especially sensitive to the level of sedation or anesthesia applied to a patient, and exhibits a distinct flattening of the waveform at a relatively light level of sedation or anesthesia, among other features.

It is further known that a 40Hz auditory signal can induce an enhanced "steady-state" AEP signal. Conventional signal averaging over a period of time is required to extract the AEP signal from background EEG signals, and adequate responses usually may be obtainable in about 30-40 seconds. The existence of an intact AEP is believed to be a highly specific indicator for the awake state of a patient, and gradual changes in the depth of sedation or anesthesia appear to be reflected by corresponding gradual changes in the AEP.

Neonatal auditory screening programs have expanded greatly in recent years because of improved auditory measurement capability, improved rehabilitation strategies, increased awareness of the dramatic benefits of early intervention for hearing impaired babies, and changes in governmental policies. An auditory abnormality is not a single, clearly defined entity with a single cause, a single referral source or a single intervention strategy. The peripheral auditory system has three separate divisions, the external ear, the middle ear, and the sensorineural portion consisting of the inner ear or cochlea, and the eighth cranial nerve. Abnormalities can and do exist independently in all three divisions and these individual abnormalities require different intervention and treatment. Poor training of technicians and improper use of the screening equipment can interact negatively to increase the total cost of an auditory screening program.

The primary economic cost of an auditory screening program is the cost of each auditory screening test. A screening test failure is usually resolved with an expensive full diagnostic test scheduled several weeks after hospital discharge, resulting in additional significant economic cost. If the initial screening false positive rate is high a substantial portion of these costs is unnecessary. High false positive rates can be particularly costly, leading to unnecessary full diagnostic tests, but they have non-economic costs as well. These non-economic costs include parental anxiety for false positive screening results, unfavorable professional perception of program effectiveness, and even inappropriate professional intervention because of misleading screening results.

These costs, both economic and non-economic, can be reduced by decreasing the cost per test, lowering the false positive rate, and resolving false positive screening results at the bedside prior to hospital discharge. Accordingly, there is a need in the medical field for life-sized anatomically correct devices that can assist in the training of technicians in the use of equipment designed to measure or monitor bioelectrical signals from an infant or patient, such as an OAE, AEP, or EEG signals.

Summary of the Invention

The present invention is a medical training device with multiple sensor contact points for providing simulated OAE and bioelectric signals to a testing or monitoring device applied to the representation by a medical technician. The sensor contact points in the medical training device are operatively coupled to one or more signal generators and a computer system, whereby simulated OAE and bioelectric signals representative of normal and abnormal patient conditions may be provided to the applied testing or monitoring device, permitting the medical technician to practice utilizing the testing or monitoring device and interpreting the results, thereby providing an improved false positive rate in practical applications.

In an embodiment of the present invention, the medical training device is in the form of a life-sized and anatomically correct representation of a human

patient's head and torso, preferably that of an infant, which includes external and internal ear structures.

In an alternate embodiment of the present invention, the medical training device is provided with an operator input configured to select the type of patient condition to be simulated in the characteristic features of the OAE and/or bioelectric signals presented for testing or monitoring at the sensor contact points.

In an alternate embodiment of the present invention, the medical training device is provided with anatomically correct representations of external mouth and nose structures. Passages within the medical training device are operatively coupled to the external mouth and nose structures, whereby breath gasses such as carbon monoxide, carbon dioxide, and oxygen can be selectively released through these passages to simulate exhaled breath for breath gas analysis training. A polychromatic component incorporated into the medical training device is correspondingly controlled to simulate one or more skin tones, representative of a variety of conditions, such as hypoxia or bilirubin presence.

The foregoing and other objects, features, and advantages of the invention as well as presently preferred embodiments thereof will become more apparent from the reading of the following description in connection with the accompanying drawings.

Brief Description of Drawings

In the accompanying drawings which form part of the specification:

Figure 1 is a graphical representation of a TEOAE response spectrum and an ambient noise spectrum;

Figure 2 is a graphical representation of a pair of test tones and a typical DPOAE response tone;

Figure 3 is a graphical representation of an auditory brainstem response to stimulus, compared with a no-stimulus signal;

Figure 4 is a simplified representation of a medical training device of the present invention;

Figure 5 is a simplified sectional view of one of the synthetic ears on the medical training device of Figure 4;

Figures 6A – 6D are simplified sectional views of an auditory probe inserted into an ear canal, including: (A) a proper coupling; (B) an inadequate seal; (C) a blocked tube; and (D) a collapsed inner ear canal;

Figure 7 is a graphical representation of an auditory evoked response over time; and

Figure 8 is a exemplary arrangement of breath gas storage and mixing components utilized to simulate exhalation.

Corresponding reference numerals indicate corresponding parts throughout the several figures of the drawings.

Best Mode for Carrying Out the Invention

The following detailed description illustrates the invention by way of example and not by way of limitation. The description clearly enables one skilled in the art to make and use the invention, describes several embodiments, adaptations, variations, alternatives, and uses of the invention, including what is presently believed to be the best mode of carrying out the invention.

Referring initially to Figure 4, a medical training simulator 10 of the present invention in the form of a life-sized and anatomically correct representation of a patient's head 12, neck 13,and upper torso 14, preferably that of an infant, is shown. The simulator 10 includes anatomical structures, such as eyes 16, ears 17, mouth 18, and nose 19. One or more electrically conductive sensor contact points 20 are provided on the surface of the simulator 10, positioned in substantially the same locations where a conventional scalp electrodes would be adhered. The device is preferably constructed from a synthetic material, having an outer covering which substantially resembles human skin, in both color and texture. Internal spaces within the simulator 10 may be filled with a rigid foam or other material to provide an internal supporting structure. Those of ordinary skill in the art will recognize that the specific dimensions, shapes, and color of the simulator 10 may be varied to provide life-sized and anatomically correct representations of patients having a

wide range of ages, from premature-birth infants to mature adults, of both genders, and of different races or ethnicities.

For devices 10 configured to represent infants, the entire body, including arms and legs may be optionally included, permitting the simulator 10 to be handled and positioned in much the same manner as a living patient would be. For example, infants are often tested in a variety of physical locations, ranging from lying inside a neonatal bassinet, to lying on a flat surface, to being held by an adult. Each of these physical locations can have significant effects on the accessibility of different points on the body for attaching screening devices, or for examination of the infant's ears. Accordingly, to provide an accurate representation of conditions which may be encountered in a practical application, the simulator 10 is preferably capable of being positioned, and being utilized, in similar physical locations with similar access constraints.

To assist in simulating conditions for auditory screening procedures, the simulator 10 is provided with anatomically correct external ears 17 coupled to anatomically correct internal ear canals 22, preferably constructed from silicone. The openings 24 to the internal ear canals 22 are preferably collapsed in a normal anatomical state, and partially occluded by the anatomically correct representation of the external pinna. During auditory testing simulation, the external pinna may be moved back in much the same manner as on a living patient, permitting access to the opening 24 and internal ear canal 22 for the insertion of an auditory probe 23 or visual inspection.

Each internal ear canal 22 opens to a cavity 26 within the simulator 10, shown in Figure 5. Preferably one cavity 26 is empty, and is adapted to provide the acoustic characteristics of a deaf ear in response to the presentation of an audible input. The cavity 26 coupled to the internal ear canal 22 on the opposite side of the head 12 is provided with a microphone 28 configured to measure audible input passing through the internal ear canal 22 from the associated opening 24, and an emitter mechanism 30 for emitting acoustic signals that are representative of otoacoustic emissions (OAE). The microphone 28 and emitter mechanism 30 are operatively coupled to a central processing unit 32 through

associated conventional electronic circuits 34. The acoustic characteristics of the internal ear canal 22 containing the microphone 28 and emitter mechanism 30 are preferably such that acoustic signals passing through the internal canal 22 are attenuated by at least 5dB over the frequency range from 1000 HZ to 8000 Hz when the internal ear canal 22 is collapsed in a natural state. Preferably, the level of attenuation is comparable to the level of attenuation found in a living patent's ear canal when it is partially or fully collapsed due to improper insertion, coupling, or blockage of an auditory screening device probe 23, such as shown in Figures 6B through 6D.

There are several conditions which can attenuate signals received at an auditory screening device probe 23. If the probe 23 is insufficiently coupled to the ear, such as shown in Figure 6B, or not coupled at all, the load acoustic impedance on the probe will be much lower than for a typical ear. Similarly, the received auditory signals will be attenuated if the sound ports of the probe are blocked either because the probe tips is against the ear canal wall, or because ear debris (cerumen, amniotic fluid, etc.) has entered one or more of the probe ports, such as shown in Figure 6C. Finally, if the probe 23 is properly coupled as shown in Figure 6A, but the ear canal has collapsed, as shown in Figure 6D, auditory signals will be attenuated when passing through the internal ear canal 22. In a preferred embodiment, the central processing unit 32 is configured to identify improper couplings between an auditory probe 23 and the ear canal 22, or to attenuate auditory signals to simulate probe blockage or collapse of the ear canal 22.

In addition to the internal ear canals 22 and associated structures for auditory screening, the simulator 10 is provided with multiple electrode sensor contact points 20 to which conventional ABR electrodes of both the disposable and non-disposable types may be attached. The sensor contact points 20 are disposed in a number of locations about the simulator 10, preferably at locations that are commonly utilized to measure and record bioelectric signals in a patent. These include the forehead, the mastoid processes of the skull, the neck 13, and the upper torso 14. The sensor contact points 20 may either be disposed directly

on the surface of the simulator 10, or alternatively, may be concealed beneath an outer layer of electrically conductive "skin" material, better simulating a living patient. Preferably, the sensor contact points 20 are selected to withstand the preparation gels and conductive pastes used with ABR screening electrodes. Each sensor contact point 20 is operatively coupled, via an associated conventional electric connection, to the CPU 32.

As shown in Figure 4, the CPU 32 is preferably external to the simulator 10, and coupled thereto via a conventional cable connection 38. The CPU 32 may consist of a general purpose computer, such as a desktop or laptop device configure with standard input and output components, or may be a dedicated computer system having only input and output components required to operate the simulator 10. In one embodiment, a separate selector unit 40 is operatively coupled to the CPU 32, and provides a plurality of operator selectable controls 42, such as dials, switches, or slides, to direct the CPU 32 to simulate responses and signals at the internal ear canal 22 elements and sensor contact points 20 which are representative of a variety of medical conditions. Alternatively, using a general purpose computer, the operator selectable controls 42 may be provided via a software application, and displayed to an operator on a display device, such as a computer monitor or LCD display device (not shown).

In the preferred embodiment, the CPU 32 is configured with one or more software modules to control the emitter mechanism 30 to generate acoustic signals in the internal ear canal 22, and conventional electrical signal generating circuits (not shown) to provide electrical signals to the electrode sensor contact points 20. Depending upon the particular type of simulation for which the simulator 10 is to be utilized, the software modules in the CPU 32 can emulate a variety of conditions which may be encountered during practical applications.

For example, for audio screening simulation, the CPU 32 and software modules receive presented audio signals and environmental noise input from the microphone 26, and control the emitter mechanism 30 to produce appropriate simulated otoacoustic emissions (OAE) in response to the presented audio signals such as tones or clicks. The CPU 32 and software modules are

configured to vary the simulated OAE produced by the emitter mechanism 30 from a "perfect" or normal OAE signal to attenuated or abnormal OAE signal representative of an auditory abnormality which may be encountered during auditory screening. The CPU and software modules may be further configured to introduce signal noise into the OAE signal, to represent practical auditory screening situations. The signal noise may be either random, i.e., white noise, or externally generated noise, i.e., recordings from actual testing environments such as hospitals, nurseries, etc.

Similarly, for audio screening simulation and brain activity simulation, the CPU 32 and software modules are configured to generate and relay both discrete and continuous bioelectric signals to the electrode sensor contact points 20 disposed about the simulator 10. In audio screening simulations, input received from the microphone 28 is utilized to initiate the generation of timed auditory evoked biopotential signals at the electrode sensor contact points 20. As shown in Figure 7, these auditory evoked biopotential signals may include representations of normal to abnormal ABR, AMLR, or ALR signals. The generated bioelectric signals may be provided to only specific electrode sensor contact points 20, or simultaneously to all electrode sensor contact points, facilitating operator training in the correct placement of electrode sensors for testing and recording specific bioelectric signals.

As with the OAE signal, the CPU and software modules may be further configured to attenuate or introduce signal noise into the auditory evoked biopotential signals, to simulate practical auditory screening situations. For brain activity simulation, such as sedation or anesthesia monitoring, these signals, generated in response to tones or pulses introduced to the internal ear canal 22, may be modified over time to simulate changes corresponding to varied levels of brain awareness. Correspondingly, simulated continuous bioelectric signals, such as brain activity, EEG, or sensory response signals may be delivered to the electrode sensor contact points 20 by the CPU 32 and software modules, and can be altered or attenuated to reflect simulated brain states.

In an alternate embodiment, the simulator 10 is further configured to provide additional functionality as a breath gas and skin tone simulator. Often, in medical procedures and examinations, there is the need to obtain measurements of the proportions and levels of gases present in the breath of a patient. Analysis of the gases present in the breath of a patient is commonly utilized as a non-invasive procedure for obtaining a representation of the proportions and levels of gases in the patient's blood. It is known that air in the deep alveolar pockets of a patient's lungs is composed of a mixture of gases which is in close equilibrium with the mixture of gases present in the patient's blood. During a patient's breath cycle, the last portion of an exhalation, i.e. the "end-tidal" portion is believed to provide the most accurate representation of the mixture of gases in the deep alveolar pockets of the lungs.

Conventional breath analyzer devices obtain a number of measurements of gas concentrations in a patient's breath over a predetermined period of time. These measurements are utilized in a mathematical curve-fitting analysis which subsequently provides an approximate measurement of the gas concentrations for discrete portions of the patients breath, including the end-tidal portion. As shown in Figure 8, to provide functionality as a breath gas simulator, the mouth 18 and nose 19 of the simulator 10 are provided with suitable openings linked via connecting tubing 102 to one or more controlled sources of breath gases. These controlled sources of breath gas consist of individual compressed gas cylinders 104, preferably of carbon monoxide, carbon dioxide, and oxygen.

In a preferred embodiment, each of the compressed gas cylinders 104 is disposed internally within the simulator 10, and selectively controlled for gas release through a valve 106 and mixing manifold 108 by the CPU 32 as directed by the selector unit 40. Alternatively, the individual compressed gas cylinders 104 may be located external to the simulator 10, and selectively coupled to the connecting tubing 102 via one or more standard hose couplings (not shown) as required, thereby permitting the simulator 10 to be more easily transported apart from the compressed gas cylinders 104.

It is further known that skin tone or color can provide a trained medical technician with useful indications as to the condition of a patient. The simulator 10 can optionally be configured to simulate a variety of skin tones or colors by incorporating a controllable polychromatic component 50 such as a color LCD screen or thermochromic plastic into a portion of the simulator 10, preferably the torso region 18 as shown in Figure 4. The polychromatic component 50 is coupled to the CPU 32 and correspondingly controlled to provide a visual simulation of one or more skin tones, representative of a variety of conditions, such as hypoxia or bilirubin presence.

During use, the simulator 10 is preferably placed in a position and orientation to simulate a likely condition in which a medical technician would be conducting an examination of a corresponding patient. Next, the simulator 10 is initialized by using the operator selectable controls 40 to determine the particular type of individual or combination simulation which will be run, i.e., auditory screening, anesthesia monitoring, sensory response signals, brain activity measurements, breath gas analysis, or skin tones. The CPU 32 and software modules selectively activate the microphone 28, the emitter mechanism 30, or the electrode sensor contact points 20 in response to the initial settings, as well as control the periodic release of breath gasses in varying concentrations from the gas cylinders 104, or simulate skin tones or colors with the polychromatic component.

To conduct a training simulation, or to test the function of an auditory screening system, bioelectric signal measurement system, or breath gas analyzer, the medical technician operates the system in a conventional manner on the activated medical simulator 10. For example, to train in the use of an auditory screening device, the medical technician might be directed to insert an auditory probe into the opening of the internal ear canal 22 on the simulator 22, and present one or more audible tones or pulses. If the technician has properly placed the auditory probe, the tones or pulses are acquired by the associated microphone 28, and passed to the CPU 32, which generates an appropriate response signal, either to the emitter mechanism 30 to present an OAE signal, or

the electrode contact points 20 to present an AEP signal. Assuming the technician has properly set up the auditory screening device, one or more of the generated response signals will be acquired by the auditory screening device, and a suitable readout presented to the technician, permitting an evaluation of the function of the screening device, and on the technicians ability to properly utilize the screening device to evoke and measure various signals.

Those of ordinary skill in the art will recognize that the medical simulator 10 of the present invention may be configured to provide a wide range of training scenarios for technicians operating medical screening devices such as auditory testing systems, anesthesia/sedation monitoring systems, or breath gas analyzers. The medical simulator 10 may be configured to provide "ideal" responses, permitting the rapid testing of the proper functioning of a properly utilized medical screening device, or may be configured to provide "real world" responses, in which signals are attenuated or mixed with noise, permitting technicians to gain practical experience related to the use of various medical screening devices.

The present invention can be embodied in the form of computer-implemented processes and apparatuses for practicing those processes. The present invention can also be embodied in the form of computer program code containing instructions embodied in tangible media, such as floppy diskettes, CD-ROMs, hard drives, or an other computer readable storage medium, wherein, when the computer program code is loaded into, and executed by, an electronic device such as a computer, micro-processor or logic circuit, the device becomes an apparatus for practicing the invention.

The present invention can also be embodied in the form of computer program code, for example, whether stored in a storage medium, loaded into and/or executed by a computer, or transmitted over some transmission medium, such as over electrical wiring or cabling, through fiber optics, or via electromagnetic radiation, wherein, when the computer program code is loaded into and executed by a computer, the computer becomes an apparatus for practicing the invention. When implemented in a general-purpose

microprocessor, the computer program code segments configure the microprocessor to create specific logic circuits.

In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results are obtained. As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.